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TRANSMITTAL  
FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission 8

Application Number	10/582,461
Filing Date	6/12/2006
First Named Inventor	Look
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	AM-101358

## ENCLOSURES (Check all that apply)

<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to TC
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment/Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
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<input type="checkbox"/> Reply to Missing Parts/Incomplete Application	Express Mail Number: EO 925 269 098 US	
<input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	Customer Number: 38199	

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	HOWSON AND HOWSON		
Signature	<i>Mary E. Bak</i>		
Printed name	Mary E. Bak		
Date	<i>Sept 28, 2006</i>	Reg. No.	31,215

## CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

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Typed or printed name		Date	

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AM-101358

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No. : 10/582,461 Confirmation No.:

Applicant : Look et al.

Filed : June 12, 2006

TC/A.U. : unassigned

Examiner : unassigned

Customer No. : 38199

Title : METHODS FOR PRODUCING STORAGE STABLE VIRUSES  
AND IMMUNOGENIC COMPOSITIONS THEREOF

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Sir:

Applicant submits to the Examiner the attached Form PTO/SB/08A/B document listing and this paper pursuant to 37 CFR § 1.56 and § 1.97-1.98. Form PTO/SB/08A/B is attached and copies of the documents are enclosed herewith. This Information Disclosure Statement is submitted more than three months from the filing date of this application, but before the receipt of a first Office Action. Therefore, no fees are believed due.

The Director is hereby authorized to charge any deficiency in any fees due with the filing of this paper or during the pendency of this application, or credit any overpayment in any fees to our Deposit Account No. 08-3040.

Express Mail No. EO 925 269 098 US

### REMARKS

Listed below are documents cited in the International Search Report dated September 9, 2005 in the corresponding International Patent Application No. PCT/US2004/041803, filed December 10, 2004. A copy of the Report is enclosed, together with copies of the documents.

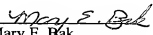
- (i) International Patent Publication No. WO 03/086443, published October 23, 2003
- (ii) US Patent No. 4,273,762, issued June 16, 1981
- (iii) MAKOSCHEY et al., "Serum-Free Produced Bovine Herpesvirus Type 1 and Bovine Parainfluenza Type 3 Virus Vaccines are Efficacious and Safe", Cytotechnol., 39(3):139-145 (2002)
- (iv) TANNOCK et al., "Freeze-Drying of Respiratory Syncytial Viruses for Transportation and Storage", J. Clin. Microbiol., 25(9):1769-1771 (1987)
- (v) PHILLIPS et al., "A Study of Water Binding in Lyophilized Viral Vaccine Systems", Cryobiology, 18(4):414-419 (August, 1981)
- (vi) International Patent Publication No. WO 02/09749, published February 7, 2002
- (vii) International Patent Publication No. WO 04/017990, published March 4, 2004
- (viii) LABCONCO, "FreeZone 1 Liter Benchtop Freeze Dry Systems: User's Manual" [Online] from [www.labconco.com/manual/freeze](http://www.labconco.com/manual/freeze), page 24, 2003
- (ix) International Patent Publication No. WO-99/62500, published December 9, 1999
- (x) JACKSON et al., "Safety of a Trivalent Live Attenuated Intranasal Influenza Vaccine, FluMist™, Administered in Addition to Parenteral Trivalent Inactivated Influenza Vaccine to Seniors with Chronic Medical Conditions", Vaccine, 17(15-16):1905-1909 (April 9, 1999)
- (xi) International Patent Publication No. WO 02/28422, published April 11, 2002

The month of publication for documents AR, AS, AV, AAR, AAU, AAW-AAV, and BW-BY could not be determined. The years of publication for documents AR, AV, AAR, AAU, AAX, and BW-BY are sufficiently earlier than the effective US filing date and/or the foreign priority date of the present application so that the particular month of publication of the documents is not in issue (MPEP 609).

The Examiner is respectfully requested to consider the enclosed document identified in this paper and in the attached Form PTO/SB/08A/B during the course of examination of this application.

Respectfully submitted,

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Attorneys for Applicants

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# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** (Use as many sheets as necessary)

Complete if Known	
Application Number	10/582,461
Filing Date	June 12, 2006
First Named Inventor	Look et al.
Art Unit	unassigned
Examiner Name	unassigned
Attorney Docket Number	AM-101358

Sheet 1 of 4

## **U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	AA	US-4,084,330	04-18-1978	FRASER	
	AB	US-5,489,266	02-06-1996	GRIMARD	
	AC	US-5,732,837	03-31-1998	JONES	
	AD	US-5,882,651	03-16-1999	MURPHY et al.	
	AE	US-5,932,222	08-03-1999	RANDOLPH et al.	
	AF	US-6,077,514	06-20-2000	MAASAB et al.	
	AG	US-6,284,254	09-04-2001	MURPHY et al.	
	AH	US-6,410,023	06-24-2002	DURBIN et al.	
	AI	US-5,993,824	11-30-1999	MURPHY et al.	
	AJ	US-4,273,762	06-16-1981	MCALIER et al.	

## **FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	†*
		Country Code <sup>2</sup> - Number <sup>3</sup> -Kind Code <sup>4</sup> (if known)				
	AL	WO-03/086443	10-23-2003	TRUONG-LE		
	AM	WO-02/09749	03-04-2004	PARRINGTON		
	AN	WO-04/017990	03-04-2004	DOMINOWSKI		
	AO	WO-99/62500	12-09-1999	VOLKIN et al.		
	AP	WO-02/28422	04-11-2002	COLAU et al.		

Examiner Signature	Date Considered
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\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		Application Number	10/582,461		
		Filing Date	June 12, 2006		
		First Named Inventor	Look et al.		
		Art Unit	unassigned		
		Examiner Name	unassigned		
Sheet	2	of	4	Attorney Docket Number	AM-101358

#### NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.†	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item, (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T‡
AR	ARYA	"Stabilization of Vaccines: To Be or Not To Be", Vaccine, 19:595-597 (2001)	
AS	CARPENTER et al.,	"5 - Rational Design of Stable Lyophilized Protein Formulations: Theory and Practice", in <u>Rational Design of Stable Protein Formulations</u> , Klumer Academic/Plenum Publishers, New York, NY: 109-33 (2002)	
AT	CHANOCK et al.,	"Serious Respiratory Tract Disease Caused by Respiratory Syncytial Virus: Prospects for Improved Therapy and Effective Immunization" Pediatrics, 90:137-142 (July 1, 1992)	
AU	CROWE et al.,	"Current Approaches to the Development of Vaccines Against Disease Caused by Respiratory Syncytial Virus (RSV) and Parainfluenza Virus (PIV): A Meeting Report from the WHO Programme for Vaccine Development" Vaccine, 13:415-421 (March, 1995)	
AV	FRANKS et al.,	"Freeze-Drying: from Empiricism to Predictability. The Significance of Glass Transitions" Dev. Biol. Stand., 74:9-18 (1992)	
AW	GLEZEN et al.,	"Risk of Respiratory Syncytial Virus Infection for Infants from Low-Income Families in Relationship to Age, Sex, Ethnic Group, and Maternal Antibody Level", J. Pediatr. 98:708-715 (May, 1981)	
AX	GUPTA et al.,	"Restoration of Suppressor T-Cell Functions in Children with AIDS Following Intravenous Gamma Globulin Treatment", Am. J. Dis. Child, 140:143-146 (February, 1986)	
AY	GUPTA et al.,	"Stabilization of RSV Against Thermal Inactivation and Freeze-Thaw Cycles for the Development and Control of RSV Vaccines and Immune Globulin" Vaccine, 14:1417-1420 (October, 1996)	
AZ	HAMBLING et al.,	"Survival of the RSV During Storage Under Various Conditions, Br. J. Exp. Pathol., 45:647-655 (December, 1964)	
AAR	HATLEY,	"The Effective Use of Differential Scanning Calorimetry in the Optimisation of Freeze-Drying Processes and Formulations", Dev. Biol. Stand. 74:105-119 (1992)	
AAS	HILLEMAN et al.,	"Improving the Heat Stability of Vaccines: Problems, Needs, and Approaches", Rev. Infect. Dis., 11(Suppl. 3): S613-616 (May-June, 1989)	
AAT	JACKSON et al.,	"Safety of a Trivalent Live Attenuated Intranasal Influenza Vaccine, FluMist™, Administered in Addition to Parenteral Trivalent Inactivated Influenza Vaccine to Seniors with Chronic Medical Conditions", Vaccine, 17(15-16): 1905-1909 (April 9, 1999)	

Examiner Signature	Date Considered
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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		Application Number	10/582,461
		Filing Date	June 12, 2006
		First Named Inventor	Look et al.
		Art Unit	unassigned
		Examiner Name	unassigned
Sheet 3 of 4	Attorney Docket Number	AM-101358	

### NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item, (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	AAU	KATZ et al., "Appendix N: Prospects for Immunizing Against Respiratory Syncytial Virus", in <i>New Vaccine Development Establishing Priorities</i> , Vol. 1, Washington, National Academic Press, pp. 397-409 (1985)	
	AAV	KNEYBER et al., "Current Concepts on Active Immunization Against Respiratory Syncytial Virus for Infants and Young Children" <i>Pediatr. Infect. Dis. J.</i> , 21(7):685-696 (July, 2002)	
	AAW	LABCONCO, "FreeZone 1 Liter Benchtop Freeze Dry Systems: User's Manual" [Online] from <a href="http://www.labconco.com/manual/freeze">www.labconco.com/manual/freeze</a> , page 24 (2003)	
	AAX	LEMON et al., "The Thermostability of Vaccines", <i>Int. J. Technol. Assess. Health Care</i> , 10(1):177-184 (1994)	
	AAY	MAKOSCHEY et al., "Serum-Free Produced Bovine Herpesvirus Type 1 and Bovine Parainfluenza Type 3 Virus Vaccines are Efficacious and Safe", <i>Cytotechnol.</i> , 39(3):139-145 (2002)	
	AAZ	MARTIN et al., "Epidemiology of Respiratory Viral Infection Among Paediatric Inpatients Over a Six-year Period in North-East England", <i>J. Lancet</i> , 1035-1038 (November 11, 1978)	
	BR	MCCONNOCHIE et al., "Variation in Severity of Respiratory Syncytial Virus Infections with Subtype", <i>J. Pediatr.</i> , 117(1):52-62 (July, 1990)	
	BS	MELNICK et al., "Effect of pH on Thermal Stabilization of Oral Poliovirus Vaccine by Magnesium Chloride", <i>Proc. Soc. Exp. Biol. Med.</i> , 112:894-897 (April, 1963)	
	BT	PHILLIPS et al., "A Study of Water Binding in Lyophilized Viral Vaccine Systems", <i>Cryobiology</i> , 18(4):414-419 (August, 1981)	
	BU	RASMUSSEN et al., "Inadequate Poliovirus Immunity Levels in Immunized Illinois Children", <i>Am. J. Dis. Child</i> , 126:465-469 (October, 1973)	
	BV	ROBBINS et al., "Obstacles to Developing Vaccines for the Third World" <i>Sc. Am.</i> , 259:126-133 (November, 1988)	
	BW	STARK et al., "Occurrence of Respiratory Syncytial Virus Subtypes in Hospitalized Children in Cleveland, Ohio from 1985-1988", <i>Pediatr. Pulmonol.</i> , 11:98-102 (1991)	

Examiner Signature	Date Considered
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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	4	of	4
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**Complete if Known**

Application Number	10/582,461
Filing Date	June 12, 2006
First Named Inventor	Look et al.
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Examiner Name	unassigned
Attorney Docket Number	AM-101358

### NON PATENT LITERATURE DOCUMENTS

[illegible]

Examiner Signature	/Myron Hill/	Date Considered	08/01/2010
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